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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,123	03/16/2001	Sharon Erickson	GENENT.073A2	6508

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1642	16

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,123	ERICKSON ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-6 and 8-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6 and 8-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group II, claims in Paper No. 9 (filed August 2, 2002) is acknowledged. Claims 3, 7, and 49-54 were canceled.

Claims 1, 2, 4-6, and 8-48 are pending and examined on the merits.

Claim Objections

2. Claim 26 is objected to for referring to Figure 1. Claims should be complete unto themselves and should not contain references to parts of the specification. To obviate this objection, the structure of DM1 should be included in the body of the claim.

Claim Rejections - 35 USC § 112

3. Claims 18, 19, 36, 43, 46, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 19, 36, 43, 46, 47 and 48 contain the trademark HERCEPTIN. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark does not identify or describe the goods associated with the

trademark. In the present case, the trademark HERCEPTIN is used to identify a humanized 4D5 antibody and, accordingly, the identification is indefinite.

4. Claims 14-16, 18, 19, 35, 36, 43, and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 14-16, 18, 19, 35, 36, 43, and 46-48 are drawn to methods using specifically named monoclonal antibodies, 4D5, 2C4, humanized 4D5 (1-8), and humanized 2C4. The specification fails to describe how to make antibodies that are exactly the same as 4D5, 2C4, humanized 4D5 (1-8), and humanized 2C4monoclonal antibody, and with exactly the same characterists. Even if the specification did provide enough information for one of skill in the art to produce a monoclonal antibody with properties similar to those of the 4D5, 2C4, humanized 4D5 (1-8), and humanized 2C4 monoclonal antibody, reproduction of an identical monoclonal antibody is an unpredictable event. Because it does not appear that the 4D5, 2C4, humanized 4D5 (1-8), and humanized 2C4 monoclonal antibody is publicly available without restriction or can be reproducibly isolated from nature without undue experimentation, one of ordinary skill in the art cannot be assured of the ability to practice the claimed inventions. Because claims 14-16, 18, 19, 35, 36, 43, and 46-48 specifically require the use of the 4D5, 2C4, humanized 4D5 (1-8), and humanized 2C4monoclonal antibody, a suitable deposit of the hybridoma producing the TG-3 monoclonal antibody is required, or evidence must be provided that the 4D5, 2C4,

humanized 4D5 (1-8), and humanized 2C4monoclonal antibody is well known and readily available to the public without any restriction, or that it is reproducible without undue experimentation.

Furthermore, unless a deposit was made at or before the time of filing, a declaration filed under the 37 C.F.R. 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited hybridoma by its depository accession number, establish that the deposited hybridoma is the same as that described in the specification, and establish that the deposited hybridoma was in applicant's possession at the time of filing. Applicant is required to amend the specification to recite the accession number of the deposit, the date of deposit, a description of the deposited biological material, and the name and address of the depository. See In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

If the deposit is made under the provision of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the Budapest Treaty as the treaty leaves this specific matter to the discretion of each member state.

If the deposits are not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit, over his or her signature and registration number, averring:

(a) that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

(b) that the material has been deposited under conditions that ensure that access to the material will be available during the pendancy of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

(c) that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

(d) that the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 4-6, 8-17, 20-35, and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chari (U.S. 6,436,931; issued Aug. 20, 2002; effective filing date Nov. 24, 1999) in view of Hudziak (U.S. ,725,856; issued Mar. 10, 1998; effective filing date Jan. 12, 1988).

Claims 1, 2, 4-6 8-43 and 46-48 are drawn to method comprising to a mammal a conjugate of an anti-ErbB2 antibody with a maytansinoid.

Chari teaches antibody conjugates to maytansinoid (abstract and claims) and methods of use (col. 8, col 16, lines 14- 54). Chari fails to teach conjugates comprising an antibody that binds to ErbB2. However, Hudziak teaches methods treating cancer comprising administering anti ErbB2 antibodies conjugated to cytotoxic agents(col. 9, line 56 – col. 10, line15). Thus, it would have been prima facie obvious to one of skill in the art at the time the invention was made to have used the teachings of Chari and of Hudziak to make the claimed inventions.

Hudziak teaches an anti-ErbB2 antibody that is growth inhibitory antibody (col. 18 – col. 19). Hudziak teaches the 4D5 monoclonal antibody. Hudziak teaches that the antibody may be an antibody fragment (col. 10, lines 14-15). Hudziak teaches specific linkers (col. 10, lines 3-14). Chari teaches specific fragments of antibodies (col. 7, lines 44-47). Chari teaches linking by a disulfide group (col. 9, lines 37-43) and other linkers (col. 15, lines 41- col. 15, line 9).

6. Claims 1, 34, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chari (U.S. 6,436,931; issued Aug. 20, 2002; effective filing date Nov. 24, 1999) in view of Hudziak (U.S. ,725,856; issued Mar. 10, 1998; effective filing date Jan. 12, 1988) in view of Kasprzyk (Cancer Res. 52: 2771-2776; cited in the IDS).

The combination of Chari and Hudziak fails to teach a method where a second anti-ErbB2 antibody is administered. However, Kasprzyk teaches the use of combinations of anti-ErbB2 antibodies in the treatment of gastric cancer. Thus, it would have been prima facie obvious at the time the invention was made to have used the teachings of Chari, Hudziak and Kasprzyk to the make the claimed inventions.

Kasprzyk teaches that growth inhibition is increased when a combination of antibodies is used compared to a single antibody treatment.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
October 21, 2002

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